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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,334	10/27/2005	Mikhail I Papisov	049479-0041(MGH 2170 US)	1459
24280 7590 05/10/2007 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER CHU, YONG LIANG	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 05/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,334	<b>Applicant(s)</b> PAPISOV ET AL.	
	<b>Examiner</b> Yong Chu	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-62 are currently pending in the instant application. The claims lack of unity of invention, and are subject to the following restriction requirement.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-62 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Due to the numerous and widely divergent generic variables in the compounds and conjugates of variable formulas, for example carrier, modifier, conjugate, and undefined M, etc., the application contains various distinct special technical features, and therefore the inventions are lack of unity. A meaningful search is impossible. A

precise listing of inventive groups cannot be made. The following groups are preliminary:

Group I: Claims 1 (in part), 2-4, 6, and 41-43 are drawn to products with **L<sup>M</sup>** as oxime-containing linker.

Group II: Claims 1 (in part), 5, and 41-43 are drawn to products with **M** as a biodegradable bond.

Group III: Claims 1 (in part), 13, and 41-43 are drawn to products with **M** as a biologically active modifier.

Group IV: Claims 1 (in part) 15, and 41-43 are drawn to products with **M** as a detectable label.

Group V: Claims 1 (in part) 17-18, and 41-43 are drawn to products with **M** as a diagnostic label.

Group VI: Claims 1 (in part), 7, and 41-43 are drawn to products with the carrier is a hydrophilic biodegradable polymer.

Group VII: Claims 1 (in part), 8, and 41-43 are drawn to products with the carrier is a naturally occurring biodegradable biocompatible homopolysaccharide.

Group VIII: Claims 1 (in part), 9, and 41-43 are drawn to products with the carrier is a naturally occurring biodegradable biocompatible heteropolysaccharide.

Group IX: Claims 1 (in part), 10, and 41-43 are drawn to products with the carrier is a hydrophilic polymer.

Group X: Claims 1 (in part), 11, and 41-43 are drawn to products with the carrier is a biodegradable biocompatible polyacetal.

Group XI: Claims 1 (in part), 12, and 41-43 are drawn to products with the carrier is a biodegradable biocompatible polyketal.

Group XII: Claims 1 (in part), 21-22, and 41-43 are drawn to products with the carrier is macromolecule.

Group XII: Claims 1 (in part), 19, and 41-43 are drawn to products with the conjugate is water-soluble.

Group XII: Claims 1 (in part), 20, and 41-43 are drawn to products with the conjugate comprises a biologically active modifier and a detachable label.

Group XIII: Claims 23, 24 and 25 are drawn to a compound having the structure  $R^{N1}R^{N2}N-O-L^1$ , wherein the variables are defined as claim 25.

Group XIV: Claims 23 and 26 are drawn to a compound having the structure  $R^{N1}R^{N2}N-O-L^1$ , wherein the variables are defined as claim 25.

Group XV: Claims 23 and 27 are drawn to a compound having the structure  $R^{N1}R^{N2}N-O-L^1$ , wherein the variables are defined as claim 27.

Group XVI: Claims 28, 29, and 31 are drawn to a compound having the structure as defined in claims 29 and 31.

Group XVII: Claims 28, 30, and 31 are drawn to a compound having the structure as defined in claims 30 and 31.

Group XVIII: Claims 28 and 31 are drawn to a compound having the structure as defined in claim 31.

Group XIX: Claims 32 and 39 are drawn to a method for preparing a conjugate having the structure as defined in claims 32 and 39.

Group XX: Claims 32 and 40 are drawn to a method for preparing a conjugate having the structure as defined in claims 32 and 40.

Group XXI: Claims 32 and 34 are drawn to a method for preparing a conjugate having the structure as defined in claims 32 and 34.

Group XXII: Claims 32, 35 and 36 are drawn to a method for preparing a conjugate having the structure as defined in claims 32, 35 and 36.

Group XXIII: Claims 33 and 34 are drawn to a method for preparing a conjugate having the structure as defined in claims 33 and 34.

Group XXIV: Claims 33, 37, and 38 are drawn to a method for preparing a conjugate having the structure as defined in claims 33, 37 and 38.

Group XXV: Claims 33 and 39 are drawn to a method for preparing a conjugate having the structure as defined in claims 33 and 39.

Group XXVI: Claims 33 and 40 are drawn to a method for preparing a conjugate having the structure as defined in claims 33 and 40.

Group XXVII: Claims 44 and 45 are drawn to a method of using a conjugate as defined in claim 1.

Group XXVIII: Claims 44 and 46 are drawn to a method of using a conjugate as defined in claim 1.

Group XXIX: Claims 44 and 47 are drawn to a method of using a conjugate as defined in claim 1.

Group XXX: Claims 44, 48 and 49 are drawn to a method of using a conjugate as defined in claim 1.

Group XXXI: Claims 44, 48 and 50 are drawn to a method of using a conjugate as defined in claim 1.

Group XXXII: Claims 51 and 52 are drawn to a method of using a conjugate as defined in claim 1.

Group XXXIII: Claims 51 and 53 are drawn to a method of using a conjugate as defined in claim 1.

Group XXXIV: Claims 54 and 55 are drawn to a method of using a conjugate as defined in claim 1.

Group XXXV: Claim 56 is drawn to a method of using a conjugate as defined in claim 54 or 51.

Group XXXVI: Claims 57 and 58 are drawn to a method of using a conjugate as defined in claim 54 or 51.

Group XXXVII: Claim 59 is drawn to a method of using a conjugate as defined in claim 54 or 51.

Group XXXVIII: Claims 60-62 are drawn to a method of using a conjugate as defined in claim 54 or 51.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. The elected group is subject to further restriction.

Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention at the similar scope as the examples shown supra (a product or a method of use of said product) by identifying another specific embodiment, i.e. another group, not listed in the exemplary groups of the invention and examiner will endeavor to group the same. ***Applicant also needs to elect a single compound as the elected species for initial search purpose.***

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature evidenced by formula I' with numerous and widely divergent variables in the compound of formula (I').

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed Yong Chu whose telephone number 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

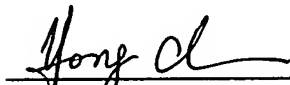
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone




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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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